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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,052

03/12/2004

William K. Keener

B-221

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05/14/2007

EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

05/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,052	KEENER, WILLIAM K.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 26 February 2007 in response to the Non-Final Office Action mailed 30 October 2006. Claims 2-5, 7-10 and 12-23 were withdrawn from consideration and claims 1, 6 and 11 were considered in the 30 October Office Action. Claims 1 and 6 were amended, claims 2-5 and 7-23 were cancelled and claims 24-26 were added in the 26 February Paper. Claims 1, 6 and 24-26 are pending and under consideration.

Response to Amendment and Arguments

Rejection of claim 11 is rendered moot by the cancellation thereof.

Specification

Objection to the abstract because it contains more than 150 words is **withdrawn** in view of the filing of a substitute abstract.

The disclosure **stands objected to** because of the following informalities: Paragraph 0042, line 3 contains misformatted text (i.e., the box between 37 and C).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Rejection of claim 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** in view of the claim amendment.

Claim 1 **stands rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons set forth in the 30 October Office Action (beginning at page 3) and herein below in the response to Applicant's arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant points out that the specification teaches that the plasmid pWKK-500 is constructed by inserting the functional elements set forth in the Application as SEQ ID NO: 2 into the commercially available base plasmid SEQ ID NO: 2. Applicant contends that one of skill in the art would appreciate that that functional elements could be cloned into plasmid pMAL-p2X using standard techniques to create plasmid pWKK-500.

This argument has been fully considered but is not deemed persuasive. As the claim is directed to an explicitly named plasmid, the enabling disclosure must teach the skilled artisan how to make a plasmid having all of the particulars of the named plasmid. Although it is clear from the disclosure that pWKK-500 comprises the vector pMAL-p2X and the various functional elements comprised by SEQ ID NO: 2, the specification does not clearly teach how these

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components are assembled to make the vector pWKK-500. For example, the disclosure does not teach precisely where the elements of SEQ ID NO: 2 are inserted into the plasmid pMAL-p2X to make the claimed pWKK-500. Even if one of skill in the art would know how to combine SEQ ID NO: 2 with pMAL-p2X in some fashion, in the absence of a complete disclosure of how all of the structural elements that make up the vector pWKK-500 are assembled (i.e., a complete nucleotide sequence) the skilled artisan would not know how to make the particular construct being claimed. Therefore, the disclosure does not enable one of skill in the art to make what is claimed.

As stated in the 30 October Office action, this rejection can be overcome by the submission of a biological deposit of the claimed plasmid pWKK-500 according to the instructions provided with the Office Action.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in reciting "the full complement of SEQ ID NO: 214". The instant application does not disclose a SEQ ID NO: 214.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Keener (2001) WO 01/60393 (of record).

Claim 25 is directed to an expression vector comprising “a polynucleotide of claim 24”. The broadest reasonable construction of “a polynucleotide of claim 24” is any polynucleotide, i.e., any two or more consecutive nucleotides, found within one of the sequences comprised by the polynucleotide of claim 24. Claim 26 is directed to a host cell transformed or transfected with the expression vector of claim 25.

In Example 3 (page 36), Keener teaches the construction of a vector for expression of a nucleic acid comprising an HIV protease cleavable linker comprising the sequence set forth therein as SEQ ID NO: 5. Keener et al further teaches expression of the construct in yeast (Example 8, page 38). SEQ ID NO: 5 of Keener comprises the sequence “gtttctcaaaa”, which is also found in the instant SEQ ID NO: 2 at positions 2191-2201. Thus, Keener teaches an expression vector comprising a polynucleotide of claim 24 operably linked to an expression control sequence and a host cell transformed therewith according to the limitations of the instant claims.

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It is noted that this rejection could be overcome by amending claim 25 to recite, "An expression vector comprising the polynucleotide of claim 24..."

Allowable Subject Matter

Claim 6 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

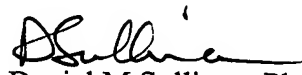
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Daniel M Sullivan, Ph.D.
Primary Examiner
Art Unit 1636